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# SECTION 2. SUMMARY AND CERTIFICATION

## 2.A. 510(k) Summary

MAY 2 3 2005

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| **Submitter:** | SterilMed, Inc. |
| **Contact Person:** | Dr. Bruce R. Lester<br>SterilMed, Inc.<br>11400 73rd Avenue North<br>Minneapolis, MN 55369<br>Ph: 763-488-3400<br>Fax: 763-488-3350 |
| **Date Prepared:** | December 28, 2004 |
| **Trade Name:** | Reprocessed Endoscopic Trocar |
| **Classification Name: and Number:** | Laparoscope, General and Plastic Surgery<br>Class II 21CFR 876.1500 |
| **Product Code:** | NLM |
| **Predicate Device(s):** | The reprocessed endoscopic trocar is substantially equivalent to the Endopath EP Disposable Surgical Trocar (K922608), manufactured by Ethicon and AutoSuture Surgiport® Endoscopic Trocar (K925860) manufactured by US Surgical. |
| **Device Description:** | Reprocessed endoscopic trocars are devices that provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures such as observation, dissecting, cutting, repairing, and removal or manipulation of internal tissues and/or organs. Reprocessed endoscopic trocars are of varying lengths and diameters, and may have either a blunt or bladed obturator tip. |

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| **Intended Use:** | The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures. |
| **Functional and Safety Testing:** | Representative samples of reprocessed endoscopic trocars underwent bench testing to demonstrate appropriate functional characteristics and biocompatibility testing to demonstrate compatibility of the device materials. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced. |
| **Conclusion:** | The reprocessed endoscopic trocars are substantially equivalent to the Endopath EP Disposable Surgical Trocar (K922608), manufactured by Ethicon and the AutoSuture Surgiport® Endoscopic Trocar (K925860), manufactured by US Surgical. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

Dr. Bruce R. Lester
Vice President, Research and Development
SterilMed, Inc.
11400 73rd Ave. North
Minneapolis, Minnesota 55369

Re: K043592
Trade/Device Name: Reprocessed Laparoscope, General and Plastic Surgery
(See enclosed list)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: NLM
Dated: April 14, 2005
Received: April 18, 2005

Dear Dr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed Laparoscope, General and Plastic Surgery (Trocar) Models found to be **Substantially Equivalent**:

1. Ethicon, 350L
2. Ethicon, 35OS
3. Ethicon, 35NST
4. Ethicon, 35NLT
5. Ethicon, 511O
6. Ethicon, 511NT
7. Ethicon, 512ON
8. Ethicon, 512NT
9. Ethicon, 355NA
10. Ethicon, 35LNA
11. Ethicon, 511NA
12. Ethicon, 512NA
13. Ethicon, 512B
14. Ethicon, 512HA
15. Ethicon, 355SD
16. Ethicon, 355LD
17. Ethicon, 578SD
18. Ethicon, 355SM
19. Ethicon, 355LM
20. Ethicon, 511SM
21. Ethicon, 512SM
22. Ethicon, 511SD
23. Ethicon, 512SD
24. Ethicon, 512XD
25. Ethicon, 355DA
26. Ethicon, 35LDA
27. Ethicon, 511DA
28. Ethicon, 355S
29. Ethicon, 355L
30. Ethicon, 511S
31. Ethicon, 512S
32. Ethicon, 512X
33. Ethicon, 355ST
34. Ethicon, 35LST
35. Ethicon, 511ST
36. Ethicon, 512ST
37. Ethicon, 355SL
38. Ethicon, 35LSL
39. Ethicon, 511SL
40. Ethicon, 512SL

Reprocessed Laparoscope, General and Plastic Surgery (Trocar) Models found to be **Substantially Equivalent** contd.:

41. Ethicon, 355HR
42. Ethicon, 511HR
43. Ethicon, 512HR
44. AutoSuture, 179776
45. AutoSuture,179777
46. AutoSuture,179770
47. AutoSuture,179771
48. AutoSuture,179074
49. AutoSuture,179076
50. AutoSuture,179077
51. AutoSuture,179070
52. AutoSuture,179071
53. AutoSuture,179078
54. AutoSuture,179070P
55. AutoSuture,179071P
56. AutoSuture,179074P
57. AutoSuture,179076P
58. AutoSuture,179077P
59. AutoSuture,179078P
60. AutoSuture,179770P
61. AutoSuture,179771P
62. AutoSuture,179776P
63. AutoSuture,179777P
64. AutoSuture,179775
65. AutoSuture,179075
66. AutoSuture,176626
67. AutoSuture,179075P
68. AutoSuture,176626P
69. AutoSuture,179775P

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# Indications for Use Page

**Device Name:** Reprocessed Endoscopic Trocars

**Indications for Use:** The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K043592